

**Center for Food Safety and Applied Nutrition
March 30-31, 2011
Food Advisory Committee Meeting
Certified Color Additives and Childhood Hyperactivity**

Charge and Questions

Charge: The task before this Food Advisory Committee is to consider available relevant data on the possible association between consumption of certified color additives in food and hyperactivity in children, and to advise FDA as to what action, if any, is warranted to ensure consumer safety. Specifically, there are several issues for which FDA would like feedback from the committee:

Question 1: In the review of published research presented in the “Overview and Evaluation of *Proposed Association Between Artificial Food Colors and Attention Deficit Hyperactivity Disorders (ADHD) and Problem Behaviors in Children*¹,” studies were evaluated based on the criteria described in Part III of the review. Were these review criteria appropriate in the evaluation of these studies? Should the criteria be modified in any specific way, and if so, how and what is the basis for the committee’s recommendation? Are there other criteria or other studies that should be considered, and if so, what is the basis for the committee’s recommendation?

Question 2: Do the current relevant data support FDA’s conclusion, as set forth in the September 1, 2010, Interim Toxicology Review Memorandum, that a causal relationship between consumption of certified color additives in food and hyperactivity in children in the general population has not been established?

Question 3: The National Institutes of Health’s 1982 Consensus Development Panel on defined diets and childhood hyperactivity concluded that for some children with both ADHD and a confirmed food allergy, dietary modification has produced some improvement in behavior². The Panel recommended that elimination diets should not be used universally to treat childhood hyperactivity (with or without the presence of food allergies), since there is no scientific evidence to predict which children may benefit. The Panel, however, also recognized that initiation of a trial of dietary treatment or continuation of a diet in patients whose families and physicians perceive benefits may be warranted. Are these conclusions and recommendations still relevant today in light of subsequently published studies, especially as those conclusions and recommendations apply to certified color additives?

¹ Provided in background materials for Committee members.

² National Institutes of Health. Defined Diets and Childhood Hyperactivity: NIH Consensus Development Conference Statement. 1982 (Jan 13-15).

Question 4: Under current FDA regulations, the label of any food to which a certified color additive has been added must declare the color additive as an ingredient by its certified name (e.g., FD&C Yellow No. 5). In light of the scientific evidence presented to the Committee concerning the consumption of certified color additives in food and hyperactivity in children, what additional information, if any, should be disclosed on the product label of foods containing certified color additives to ensure their safe use in food?

Question 5: Regarding the possible association between consumption of certified color additives and hyperactivity in children, are additional studies necessary to address any questions that have been raised as to whether, and under what conditions, the continued use of these certified color additives is safe? If so, what type of studies?